

IN THE UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,  
CALIFORNIA, COLORADO,  
CONNECTICUT, DELAWARE, DISTRICT  
OF COLUMBIA, FLORIDA, GEORGIA,  
HAWAII, ILLINOIS, INDIANA, IOWA,  
LOUISIANA, MARYLAND,  
MASSACHUSETTS, MICHIGAN,  
MINNESOTA, MONTANA, NEVADA, NEW  
JERSEY, NEW MEXICO, NEW YORK,  
NORTH CAROLINA, OKLAHOMA, RHODE  
ISLAND, TENNESSEE, TEXAS, VIRGINIA,  
WISCONSIN

*Ex rel.* CATHLEEN FORNEY

Plaintiffs,

vs.

MEDTRONIC, INC.,

Defendant.

Case No. 5:15-cv-6264-EGS

STIPULATED [PROPOSED] PROTECTIVE  
ORDER

The Court recognizes that many of the documents and much of the information being sought through discovery in the above-captioned action are, for competitive reasons, normally kept confidential by the parties. The materials to be exchanged throughout the course of the litigation between the parties may contain trade secret or other confidential research, development, or commercial information, as is contemplated by Federal Rule of Civil Procedure 26(c)(1)(G). Furthermore, information to be exchanged in this litigation will likely include Confidential Health Information (as defined herein). Accordingly, there is “good cause” to enter a protective order. *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994). The parties have agreed to be bound by the terms of this Protective Order (“Order”) in this action to facilitate the document production and disclosure, and to protect the respective interests of the parties in their trade secrets

and/or confidential information. This Order shall remain in effect unless modified pursuant to the terms contained in this Order.

IT IS THEREFORE ORDERED THAT,

The following Definitions shall apply in this Order:

A. The term “**Confidential Information**” will mean and include:

1. Information contained or disclosed in any materials, including documents, portions of documents, answers to interrogatories, responses to requests for admissions, trial testimony, deposition testimony, and transcripts of trial testimony and depositions, including data, summaries, and compilations derived therefrom that is deemed to be Confidential Information by any party to which it belongs.

2. “**Confidential Health Information**,” which, pursuant to 45 C.F.R. § 164.512(e)(1), will mean and include “protected health information” and “individually identifiable health information” as such terms are defined in 45 C.F.R. § 160.103 in the General Administrative Requirements promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended. Confidential Health Information includes, but is not limited to, any document or information supplied in any form, or any portion thereof, that identifies an individual in any manner and related to (a) the past, present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, (b) the provision of health care to such individual, or (c) the past, present, or future payment for the provision of health care to such individual. Confidential Health Information also includes, but is not limited to, medical bills, claims forms, charge sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanations of benefits, checks, notices, requests, and social security numbers or similar information. Confidential Health

Information includes all notes, summaries, compilations, extracts, abstracts, or oral communications that contain, are based on, or are derived from Confidential Health Information but does not include any of the above where such does not include individual identifiers and is fully de-identified in accordance with the HIPAA de-identification standard set forth in 45 C.F.R. § 164.514(a). Confidential Health Information also includes any materials subject to the provisions of any other applicable federal law, including but not limited to the Privacy Act, 5 U.S.C. § 552a, or the privacy laws of any individual states as applicable.

B. The term “**Counsel**” will mean outside counsel of record, and other attorneys, paralegals, secretaries, vendors, and other support staff employed by the following law firms: Ropes & Gray LLP; Pepper Hamilton LLP; the Law Offices of Susan L. Burke; and Gross McGinley, LLP.

The following provisions shall apply in this litigation:

1. Each party to this litigation that produces or discloses any Confidential Information or Confidential Health Information may designate the same as “CONFIDENTIAL.”
2. Each party to this litigation that produces or discloses Confidential Information or Confidential Health Information may designate the same as “CONFIDENTIAL – FOR COUNSEL ONLY” if, in the good faith belief of such party and its Counsel, the information is among that considered to be most sensitive by the party, including but not limited to trade secret or other confidential research, development, financial, customer-related data or other commercial information.
3. Before any documents designated as “CONFIDENTIAL” or “CONFIDENTIAL – FOR COUNSEL ONLY” are filed with the Court for any purpose, the party seeking to file such documents must notify the opposing party at least ten (10) days before the filing. The opposing

party will then have five (5) business days to evaluate the request and determine whether the documents should retain their confidentiality designations and whether any documents should be filed under seal. If the opposing party determines that documents should be filed under seal, the opposing party will be responsible for obtaining permission from the Court for filing the documents under seal for good cause shown, pursuant to Local Rule 5.1.5.(a)(2).

4. Whenever a deposition taken on behalf of any party involves the disclosure of Confidential Information or Confidential Health Information of any party:

- (a) the deposition or portions of the deposition must be designated as “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY,” as appropriate, subject to the provisions of this Order; such designation must be made on the record whenever possible, but a party will have until thirty (30) days after receipt of the deposition transcript to inform the other party or parties to the action of the portions of the transcript to be designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY”;
- (b) the disclosing party will have the right to exclude from attendance at the deposition, during such time as the Confidential Information is to be disclosed, any person other than the deponent, Counsel (including their staff and associates), the court reporter, and the person(s) identified in paragraphs 6 and 7, below; and
- (c) the original or any copy of a deposition transcript designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY,” must not be filed with this Court unless it can be accomplished under seal, identified as being subject to this Order, and protected from being opened except by order of this Court.

5. All Confidential Information or Confidential Health Information designated as “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” must not be disclosed by the receiving party to anyone other than those persons designated within this Order and must be handled in the manner set forth below, and in any event, must not be used for any purpose other than in connection with this litigation, unless and until such designation is removed either by agreement of the parties, or by order of the Court. All “covered entities” (as defined by 45 C.F.R. § 160.103) are hereby authorized to disclose Confidential Information, including Confidential Health Information, pertaining to this action to those persons designated in Paragraph 7 below. Such persons shall be permitted to use or disclose the Confidential Information for purposes of litigating this action, including any appeals of this case. This Order does not limit or control the use of protected health information pertaining to this case that comes into the possession of the parties or their attorneys from a source other than a “covered entity,” as that term is defined in 45 C.F.R. § 160.103. Nothing in this Order authorizes the parties or their attorneys to obtain medical records or other information through means other than formal discovery requests, subpoenas, depositions, pursuant to a patient authorization, or other lawful process.

6. All Confidential Information or Confidential Health Information designated “CONFIDENTIAL — FOR COUNSEL ONLY” may be viewed only by:

- (a) Counsel (as defined in paragraph C, above) of the receiving party;
- (b) Independent experts and stenographic and clerical employees associated with such experts. Prior to receiving any Confidential Information of the producing party, the expert must execute a copy of the “Agreement to Be Bound by Stipulated Protective Order,” attached hereto as Exhibit A. Counsel for the receiving party must retain executed copies of such exhibits;
- (c) The Court and any Court staff and administrative personnel;

- (d) Any court reporter employed in this litigation and acting in that capacity; and
- (e) Any person indicated on the face of the document to be its author or co-author, or any person identified on the face of the document as one to whom a copy of such document was sent before its production in this action.

7. All Confidential Information or Confidential Health Information designated “CONFIDENTIAL” may be viewed only by the individuals listed in paragraph 6, above, and by the additional individuals listed below:

- (a) Party principals or executives who are required to participate in policy decisions with reference to this action;
- (b) The individual parties to the case;
- (c) Technical personnel of the parties with whom Counsel for the parties find it necessary to consult, in the discretion of such Counsel, in preparation for trial of this action; and
- (d) Stenographic and clerical employees associated with the individuals identified above.

8. All Confidential Information or Confidential Health Information designated “CONFIDENTIAL — FOR COUNSEL ONLY” by the producing or disclosing party, and any and all reproductions of that information, must be retained in the custody of the Counsel for the receiving party, except that independent experts authorized to view such information under the terms of this Order may retain custody of copies such as are necessary for their participation in this litigation, but only during the course of this litigation. The principals, employees or other agents of the parties who received information prior to and apart from this litigation that was subsequently disclosed in this litigation as being either “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” may also retain copies of that information as is necessary for use in their respective businesses.

9. All Confidential Information or Confidential Health Information designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” shall be used solely for the prosecution or defense of this action. A party who wishes to use information designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” for a purpose other than the prosecution or defense of this action must request permission, in writing, from Counsel for the producing party. The receiving party’s request must identify the Confidential Information or Confidential Health Information designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” that the receiving party wishes to use, and identify the purpose for which it wishes to use Confidential Information or Confidential Health Information designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY.” If the parties cannot resolve the question of whether the receiving party can use Confidential Information or Confidential Health Information designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” for a purpose other than the prosecution or defense of this action within fourteen (14) days of the producing party’s receipt of such a request, the receiving party may move the Court for a ruling on the receiving party’s request. In the event any party files a motion seeking to use Confidential Information or Confidential Health Information designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” for a purpose other than the prosecution or defense of this action, the Confidential Information or Confidential Health Information designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” shall be submitted to the Court, under seal, for an in-camera inspection. The information at issue designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” must be treated as “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY”, as designated by the producing party, until the Court has ruled on the motion or the matter has been otherwise resolved.

10. Third parties producing documents in the course of this action may also designate documents as “CONFIDENTIAL,” subject to the same protections and constraints as the parties to the action. A copy of the Protective Order shall be served along with any subpoena served in connection with this action. All documents produced by such third parties shall be treated as “CONFIDENTIAL” for a period of 14 days from the date of their production, and during that period any party may designate such documents as “CONFIDENTIAL” pursuant to the terms of the Protective Order.

11. At any stage of these proceedings, any party may object to a designation of information as “CONFIDENTIAL” or “CONFIDENTIAL —FOR COUNSEL ONLY.” The party objecting to confidentiality must notify, in writing, Counsel for the producing party of the objected-to designation and the grounds for the objection. If the dispute is not resolved consensually between the parties within ten (10) days of receipt of such a notice of objections, the objecting party may move the Court for a ruling on the objection. In the event any party files a motion challenging the designation or redaction of information, the document shall be submitted to the Court, under seal, for an in-camera inspection. The information at issue designated “CONFIDENTIAL” or “CONFIDENTIAL —FOR COUNSEL ONLY” must be treated as “CONFIDENTIAL” or “CONFIDENTIAL —FOR COUNSEL ONLY”, as designated by the producing party, until the Court has ruled on the motion or the matter has been otherwise resolved.

12. At any stage of these proceedings, any party may request that it be permitted to disclose information designated as “CONFIDENTIAL” or “CONFIDENTIAL —FOR COUNSEL ONLY” to individuals not permitted by this Order to view such information. The party must notify, in writing, Counsel for the producing party of the information to be disclosed and the identities of the proposed individuals to whom the party wishes to make the disclosure. If the request is not resolved consensually between the parties within fourteen (14) days of receipt of such a request, the



requesting party may move the Court for a ruling allowing such disclosure. In the event any party files a motion requesting such disclosure, the document shall be submitted to the Court, under seal, for an in-camera inspection. The information at issue designated “CONFIDENTIAL” or “CONFIDENTIAL —FOR COUNSEL ONLY” must be treated as “CONFIDENTIAL” or “CONFIDENTIAL —FOR COUNSEL ONLY”, as designated by the producing party, until the Court has ruled on the motion or the matter has been otherwise resolved.

13. All Confidential Information must be held in confidence by those inspecting or receiving it. To the extent the Confidential Information has not been disclosed prior to and apart from this litigation, it must be used only for purposes of this action. If the Confidential Information was exchanged between the parties prior to and apart from this litigation for purposes of conducting their respective businesses, the parties may continue to use that otherwise Confidential Information for that purpose. The parties may not distribute the Confidential Information beyond those persons or entities that had received the Confidential Information prior to this litigation. In addition, counsel for each party, and each person receiving Confidential Information, must take reasonable precautions to prevent the unauthorized or inadvertent disclosure of such information. If Confidential Information is disclosed to any person other than a person authorized by this Order, the party responsible for the unauthorized disclosure must immediately bring all pertinent facts relating to the unauthorized disclosure to the attention of the other parties and, without prejudice to any rights and remedies of the other parties, make every effort to prevent further disclosure by the party and by the person(s) receiving the unauthorized disclosure.

14. No party will be responsible to another party for disclosure of Confidential Information under this Order if the information in question is not designated or otherwise identified as such in accordance with this Order.

15. If a party, through inadvertence, produces any Confidential Information or Confidential Health Information without labeling or marking or otherwise designating it as “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” in accordance with this Order, the producing party may give written notice to the receiving party that the information produced should be treated as though it were designated “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY,” as appropriate, under this Order, and the information must be so treated upon receipt of such written notice. If the receiving party has disclosed the information at issue before receiving written notice of the designation, the receiving party must notify the producing party in writing of each such disclosure. Counsel for the parties will agree on a mutually acceptable manner of labeling or marking the inadvertently produced materials as “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY.”

16. Nothing within this Order will prejudice the right of any party to object to the production of any discovery material on the grounds that the material is protected as privileged or as attorney work product.

17. Nothing in this Order will bar Counsel from rendering advice to their clients with respect to this litigation and, in the course thereof, relying upon any information designated as “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” provided that the contents of the information must not be disclosed except as otherwise provided herein.

18. This Order will be without prejudice to the right of any party to oppose production of any information for lack of relevance or any other ground other than the mere presence of Confidential Information. The existence of this Order must not be used by either party as a basis for discovery that is otherwise improper under the Federal Rules of Civil Procedure.

19. Information designated CONFIDENTIAL pursuant to this Order also may be disclosed if: (a) the party or non-party making the designation consents to such disclosure; (b) the

Court, after notice to all affected persons, allows such disclosure; or (c) the party to whom Confidential Information has been produced thereafter becomes obligated to disclose the information in response to a lawful subpoena, provided that the subpoenaed party gives prompt notice to Counsel for the party which made the designation, and permits Counsel for that party sufficient time to intervene and seek judicial protection from the enforcement of this subpoena and/or entry of an appropriate protective order in the action in which the subpoena was issued.

20. Nothing in this Confidentiality Order shall limit any producing party's use of its own documents or shall prevent any producing party from disclosing its own Confidential Information to any person. Such disclosures shall not affect any confidential designation made pursuant to the terms of this Order so long as the disclosure is made in a manner which is reasonably calculated to maintain the confidentiality of the information.

21. Within sixty (60) days of the final termination of this action, including any and all appeals, Counsel for each party must purge all materials designated "CONFIDENTIAL" or "CONFIDENTIAL — FOR COUNSEL ONLY" from all machine-readable media on which it resides and must either (a) return all materials designated "CONFIDENTIAL" or "CONFIDENTIAL — FOR COUNSEL ONLY" to the party that produced the information, including any copies, excerpts, and summaries of that information, or (b) destroy same. With respect to paper copies, return or destruction of materials designated "CONFIDENTIAL" or "CONFIDENTIAL — FOR COUNSEL ONLY" is at the option of the producing party. Notwithstanding the foregoing, Counsel shall be entitled to retain attorney work product and, for archival purposes, paper and electronic copies of pleadings, correspondence, transcripts, exhibits, and memoranda that contain or refer to Confidential Information or Confidential Health Information, including a complete record of any proceedings before the Court, and will continue to be bound by this Order with respect to all such retained information, after the conclusion of this litigation.

22. Notwithstanding the foregoing Paragraph, Parties, their Counsel, and others identified in Paragraphs 6 and 7 shall not be required to delete electronic information that may reside on their respective electronic archives or disaster recovery systems. However, Parties, their Counsel, and others shall not retrieve any Confidential Information from such systems after the conclusion of the Matter.

23. The restrictions and obligations set forth within this Order will not apply to any information that: (a) the parties agree should not be designated Confidential Information; (b) the parties agree, or the Court rules, is already public knowledge; or (c) the parties agree, or the Court rules, has become public knowledge other than as a result of disclosure by the receiving party, its employees, or its agents, in violation of this Order.

24. Transmission by e-mail or facsimile is acceptable for all notification purposes within this Order.

25. This Order may be modified by agreement of the parties, subject to approval by the Court.

26. The Court may modify the terms and conditions of this Order for good cause, or in the interest of justice, or on its own order at any time in these proceedings.

27. After termination of this action, the provisions of this Order shall continue to be binding, except with respect to those documents and information that became a matter of public record. This Court retains and shall have continuing jurisdiction over the parties and recipients of Confidential Information and information designated as “CONFIDENTIAL” or “CONFIDENTIAL — FOR COUNSEL ONLY” for enforcement of the provisions of this Order following termination of this litigation.

Dated: October 5, 2017

Respectfully submitted,

/s/ Kirsten V. Mayer

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*Attorneys for Defendant Medtronic, Inc.*

So Ordered:

A handwritten signature in black ink, appearing to be 'E. Smith', written over a horizontal line.

Hon. Edward Smith  
UNITED STATES DISTRICT COURT JUDGE

IN THE UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,  
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Case No. 5:15-cv-6264-EGS

**DRAFT STIPULATED [PROPOSED]  
PROTECTIVE ORDER**

**EXHIBIT A**

**WRITTEN ASSURANCE**

\_\_\_\_\_ declares that:

I reside at \_\_\_\_\_ in the City of  
\_\_\_\_\_, County of \_\_\_\_\_, State of \_\_\_\_\_. My telephone  
number is \_\_\_\_\_.

I am currently employed by \_\_\_\_\_, located at  
\_\_\_\_\_, and my current job title is  
\_\_\_\_\_.

I have read and I understand the terms of the Protective Order dated \_\_\_\_\_,  
filed in Case No. 15-cv-6264, pending in the United States District Court for the District of Eastern

Pennsylvania. I agree to comply with and be bound by the provisions of the Protective Order. I understand that any violation of the Protective Order may subject me to sanctions by the Court.

I shall not divulge any documents, or copies of documents, designated "Confidential" obtained pursuant to such Protective Order, or the contents of such documents, to any person other than those specifically authorized by the Protective Order. I shall not copy or use such documents except for the purposes of this action and pursuant to the terms of the Protective Order.

As soon as practical, but no later than 60 days after final termination of this action, I shall return to the attorney from whom I have received them, any documents in my possession designated "Confidential", and all copies, excerpts, summaries, notes, digests, abstracts, and indices relating to such documents.

I submit myself to the jurisdiction of the United States District Court for the District of Eastern Pennsylvania for the purpose of enforcing or otherwise providing relief relating to the Protective Order.

Executed on \_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Signature)